Complete Summary

GUIDELINE TITLE

Caesarean section.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Caesarean section. London (UK): National Institute for Clinical Excellence (NICE); 2004 Apr. 142 p. [688 references]

GUI DELI NE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA

determines pose a serious and significant public health concern. See the <u>FDA Web</u> site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Conditions for which women should be offered planned Caesarean section (CS)
- Conditions for which women should not be normally offered planned CS
- Conditions that affect likelihood of CS
- Childbirth

GUIDELINE CATEGORY

Counseling

Evaluation

Management

Risk Assessment

CLINICAL SPECIALTY

Anesthesiology

Family Practice

Internal Medicine

Obstetrics and Gynecology

Pediatrics

INTENDED USERS

Advanced Practice Nurses Health Care Providers Hospitals Nurses

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Patients

GUIDELINE OBJECTIVE(S)

- To help ensure consistency of quality of care experienced by women having Caesarean section (CS)
- To provide evidence based information for health care professionals and women about:
 - the risks and benefits of CS
 - certain specific indications for CS
 - effective management strategies which avoid CS
 - anaesthetic and surgical aspects of care
 - interventions to reduce morbidity from CS
 - aspects of organisation and environment which affect CS rates

TARGET POPULATION

- Pregnant women who are making decisions about mode of delivery, and women undergoing or who have undergone Caesarean section
- Newborn babies delivered by Caesarean section

INTERVENTIONS AND PRACTICES CONSIDERED

Making the Decision for Caesarean Section (CS)

- 1. Providing information on risks and benefits of CS to the pregnant woman in an accessible form
- 2. Offering planned CS to women based on maternal and neonatal risk
- 3. Reducing likelihood of CS by offering external cephalic version to women with uncomplicated singleton breech pregnancy, offering women continuous support during labour, offering induction of labour beyond 41 weeks, monitoring progress of labour, involving a consultant obstetrician in decision for CS, and using fetal blood sampling for suspected acidosis
- 4. Requesting and obtaining consent for CS
- 5. Timing of planned CS (after 39 weeks' gestation)
- 6. Documenting urgency of CS
- 7. Performing emergency CS as soon as possible

Procedural Aspects of CS

- 1. Preoperative assessment
 - Hemoglobin check
 - Prescription of antibiotics
 - Assessment of risk for thromboembolic disease
 - Use of indwelling bladder catheter

Note: Grouping and saving of serum, cross-matching of blood, clotting screen, and preoperative ultrasound to localize the placenta are not recommended for healthy women with an uncomplicated pregnancy.

2. Anesthetic care

- Discussion of post-CS anesthesia
- Offering antacids and H₂ receptor antagonists
- Offering antiemetics
- Offering regional anesthesia
- · Reducing risk of hypotension by using
 - Intravenous ephedrine or phenylephrine infusion
 - Volume preloading with crystalloid or colloid
 - Lateral lift of 15 degrees
- Preoxygenation and rapid sequence induction during general anesthesia for emergency CS
- Maternity unit drills for failed intubation

3. Surgical techniques

- Use of double gloves in women who are human immunodeficiency virus (HIV) positive
- Use of transverse lower abdominal incision
- Use of blunt extension of the uterine incision
- Use of oxytocin
- Use of controlled cord traction for removal of the placenta
- Closure of incision with two suture layers
- Checking of umbilical artery pH
- Considering woman's preference for birth environment and facilitating skin-to-skin contact for mother and baby

Note: The following interventions and procedures are not recommended: closure of the subcutaneous space (unless >2 cm fat); use of superficial wound drains; use of separate surgical knives for skin and deeper tissues; use of forceps routinely to deliver baby's head; suturing either the visceral or the parietal peritoneum; exteriorising the uterus; manual removal of the placenta

- 4. Postoperative monitoring, including monitoring of cardiorespiratory stability, degree of sedation, and pain control
- 5. The resuscitation of the newborn at CS with a general anaesthetic or with presumed fetal compromise
- 6. Care of women and baby after CS, including support for breastfeeding, supplemental analgesia, wound care, discharge options
- 7. Monitoring of recovery following CS, including wound care and maintaining vigilance for complications
- 8. Discussion of implications for future vaginal births

MAJOR OUTCOMES CONSIDERED

- Caesarean section (CS) rate
- Perinatal mortality
- Neonatal morbidity and mortality
- Maternal morbidity and mortality
- Mother-to-child viral transmission (human immunodeficiency virus, hepatitis B, hepatitis C, and genital herpes simplex virus)
- Respiratory morbidity
- Operating time
- Length of hospital stay and readmission to hospital

- Overall benefits and risks
- Wound infection
- Pain
- Breastfeeding rate
- Cost-effectiveness of vaginal birth after CS versus repeat CS
- Costs of maternal request for CS

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

The aim of the literature review was to identify and synthesize relevant evidence within the published literature, in order to answer specific clinical questions. Searches were performed using generic and specially developed filters, relevant medical subject heading terms, and free-text terms. Details of all literature searches are available on application to the National Collaborating Centre for Women's and Children's Health.

The National Guidelines Clearinghouse database, the Turning Research into Practice database, and the Organising Medical Networked Information service on the Internet were searched for guidelines produced by other development groups. The reference lists in these guidelines were checked against the Guideline Development Group's searches to identify any missing evidence.

Searches were carried out for each topic of interest. The Cochrane Library (up to Issue 4, 2003) was searched to identify systematic reviews (with or without meta-analyses) of randomised controlled (clinical) trials (RCTs) and individual RCTs. The electronic databases MEDLINE (Ovid version for the period January 1966 to January 2004), EMBASE (Ovid version for the period between 1988 to January 2004), the Cumulative Index to Nursing and Allied Health Literature, the British Nursing Index, and PsychInfo were also searched, as was the Database of Abstracts and Reviews of Effectiveness.

There was no systematic attempt to search the grey literature (conferences, abstracts, theses and unpublished trials).

A preliminary scrutiny of titles and abstracts was undertaken and full papers were obtained if the research question addressed the Guideline Development Groups question relevant to the topic. Following a further review of the full version of the study, articles that did not address the Groups question were excluded. Studies that did not report relevant outcomes were also excluded. Submitted evidence from stakeholders was included where the evidence was relevant to the Groups

clinical question and was of equivalent or better quality than the research identified in the literature searches.

The economic evidence presented in this guideline is not a systematic review of all the economic evidence around CS, but a review of evidence relating to specific aspects of CS. In addition to the databases listed above, the Health Economic Evaluations Database and the NHS Economic Evaluations Database were searched for relevant economic studies.

The search strategies were designed to find any economic study related to CS. Relevant references in the bibliographies of reviewed papers were also identified. Abstracts and database reviews of papers found were reviewed by the health economists and were excluded if they appeared not to contain any cost data relevant to the UK setting or did not relate to the precise topic or question being considered. Studies were included if they focused on the appropriate clinical question and were generalisable to the England and Wales setting. The review of the evidence included cost-effectiveness studies, cost-consequence studies (cost of present and future costs only) and high quality systematic reviews of the evidence.

For all subject areas, evidence from the study designs least subject to bias was included. Where possible, the highest levels of evidence were used, but all papers were reviewed using established guides. Published systematic reviews or meta-analyses were used where available. For subject areas where neither was available, other appropriate experimental or observational studies were sought.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1a: Evidence obtained from systematic review or meta-analysis of randomised controlled trials

1b: Evidence obtained from at least one randomised controlled trial

2a: Evidence obtained from at least one well-designed controlled study without randomisation

2b: Evidence obtained from at least one well-designed quasi-experimental study, such as a cohort study

- 3: Evidence obtained from well-designed nonexperimental descriptive studies, such as comparative studies, correlation studies, case-control studies, and case series
- 4: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Identified articles were assessed methodologically and the best available evidence was used to form and support the recommendations. The highest level of evidence was selected for each clinical question. The retrieved evidence was graded according to the evidence-level structure shown in the field "Rating Scheme for the Strength of the Evidence" in the complete summary. The clinical question dictated the highest level of evidence that could be sought. For issues of therapy or treatment the highest possible level of evidence was a meta-analysis of randomised controlled trials (RCT) or an individual RCT.

For issues of prognosis, a cohort study was the best possible level of evidence. This equates to a grade B recommendation. However, this should not be interpreted as an inferior grade of recommendation because it represents the highest level of evidence attainable for that type of clinical question.

For diagnostic tests, test evaluation studies examining the performance of the test were used if the efficacy of the test was required, but where an evaluation of the effectiveness of the test in the management and outcome was required, evidence from RCTs or cohort studies was sought. For questions about women's beliefs, attitudes, and experiences of childbirth and CS, qualitative research was reviewed.

All retrieved articles were appraised methodologically using established guides. Where appropriate, if a systematic review, meta-analysis, or RCT existed in relation to a topic, studies of a weaker design were excluded. The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers in the form of evidence tables and agreeing brief statements that accurately reflected the relevant evidence. Quantitative synthesis (meta-analysis) was performed where appropriate. Meta-analyses based on dichotomous outcomes are presented as relative risks with 95% confidence intervals.

For the purposes of this guideline, data are presented as absolute risks, relative risks, or odds ratios where relevant (i.e., in RCTs and cohort studies). Where the data are statistically significant, they are also presented as numbers needed to treat (for beneficial outcomes) or numbers need to harm (for adverse effects of treatment) if relevant.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group [GDG]) convened by the National Collaborating Centre for Women's and Children's Health (NCC-WCH).

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval, and appraisal of the evidence, and wrote successive drafts of the document.

The Guideline Development Group was presented with the summaries (text and evidence tables) of the best available research evidence to answer each clinical question.

Recommendations were based on, and explicitly linked to, the evidence that supported them. Where possible, the Group worked on an informal consensus basis. Formal consensus methods (the nominal group technique) were employed when required (e.g., grading recommendations and agreeing audit criteria).

Summary results are presented in the original guideline document. More detailed results and other data are presented in the relevant evidence tables accompanying the original guideline document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grading of recommendations follows that outlined in the Health Technology Assessment How to Develop Cost-Conscious Guidelines:

Grade A Based directly on level 1 evidence

Grade B Based directly on level 2 evidence or extrapolated from level 1 evidence

Grade C Based directly on level 3 evidence or extrapolated from level 1 or level 2 evidence

Grade D Based directly on level 4 evidence or extrapolated from level 1, level 2, or level 3 evidence

GPP Good Practice Point based on the view of the Guideline Development Group

COST ANALYSIS

The purpose of including economic evidence in a clinical guideline is to allow recommendations to be made not just on the clinical effectiveness of different

forms of care, but also on their cost effectiveness. The aim is to produce guidance that uses scarce health service resources efficiently, that is providing the best possible care within resource constraints.

There is economic literature that has considered the economic costs and consequences of different modes of birth. The economic evidence is focused around the cost of Caesarean section (CS) compared to vaginal birth. The economic evidence presented in this guideline is not a systematic review of all the economic evidence around CS. Specific topics were considered where it was thought that economic evidence would help them to inform decision making.

Topics for economic analysis were selected on the following basis by the guideline development group:

- Does the proposed topic have major resource implications?
- Is there a change of policy involved?
- Are there sufficient data of adequate quality to allow useful review or modelling?
- Is there a lack of consensus amongst clinicians?
- Is there a particular area with a large amount of uncertainty?

Where the above answers are yes, this indicated that further economic analysis including modelling was more likely to be useful.

A simple economic model was developed for each of the specific topic areas for which the economic evidence was reviewed, in order to present the guideline development group with a coherent picture of the costs and consequences of the decisions based on the clinical and economic evidence. The health economist undertook the literature review in these specific areas and obtained cost data considered to be the closest to current UK opportunity cost (the value of the resources used, rather than the price or charge). The criteria for assessing the economic papers was based on that developed by Drummond et al (1997) and the format of the abstract follows that of the National Health Service Economic Evaluation Database (NHS EED) managed by the NHS Centre for Reviews and Dissemination (http://www.york.ac.uk/inst/crd/crddatabases.htm)

Health economics evidence was available for the following areas:

- External cephalic version for breech presentation at term
- CS in the management of women with breech presentation
- Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)
- Herpes simplex virus
- Vaginal birth after CS
- Maternal request for CS
- Use of antibiotics at CS
- Intrathecal diamorphine

The economic evidence is based not only on the economic literature, but is also consistent with the clinical effectiveness evidence presented in the guideline.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline has been developed in accordance with the National Institute for Clinical Excellence (NICE) guideline development process. This has included the opportunity for registered stakeholders to comment on the scope of the guideline, the first draft of the full and summary guidelines and the second draft of all versions of the guideline. In addition the drafts were reviewed by an independent Guideline Review Panel and the Patient Involvement Unit established by NICE. The summary of recommendations was reviewed by the NICE Executive.

The comments made by the stakeholders, peer reviewers, the Guideline Review Panel, and NICE were collated and presented anonymously for consideration by the Guideline Development Group. All comments were considered systematically by the Guideline Development Group and the resulting actions and responses were recorded.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (1a-4) and grading of recommendations (A-D) are defined at the end of the Major Recommendations field.

In addition to the evidence-based recommendations, the guideline development group also identifies points of good clinical practice (GPP).

Woman-centered Care

Provision of Information

C - Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about childbirth. Addressing women's views and concerns should be recognised as being integral to the decision-making process.

GPP - Pregnant women should be given evidence-based information about caesarean section (CS) during the antenatal period, because about 1 in 5 women will have a CS. This should include information about CS such as:

- indications for CS (such as presumed fetal compromise, failure to progress in labour, breech presentation)
- what the procedure involves
- associated risks and benefits
- implications for future pregnancies and birth after CS

GPP - Communication and information should be provided in a form that is accessible to pregnant women, taking into account the information and cultural needs of minority communities and women whose first language is not English or who cannot read, together with the needs of women with disabilities or learning difficulties.

Information summarising the likely effect of CS on women's and children's health can be found in Appendix A of the original guideline document.

Consent for Caesarean Section (CS)

- C Consent for CS should be requested after providing pregnant women with evidence-based information and in a manner that respects the woman's dignity, privacy, views, and culture, while taking into consideration the clinical situation.
- D A competent pregnant woman is entitled to refuse the offer of treatment such as CS, even when the treatment would clearly benefit her or her baby's health. Refusal of treatment needs to be one of the patient's options.
- GPP When considering a CS, there should be discussion on the benefits and risks of CS compared with vaginal birth specific to the woman and her pregnancy.
- GPP When the decision is made to perform a CS, a record should be made of all the factors that influence the decision, and which of these is the most influential.

Classification of Urgency

- C The urgency of CS should be documented using the following standardised scheme in order to aid clear communication between health-care professionals about the urgency of a CS:
- 1. Immediate threat to the life of the woman or fetus
- 2. Maternal or fetal compromise which is not immediately life-threatening
- 3. No maternal or fetal compromise but needs early delivery
- 4. Delivery timed to suit woman or staff

Planned CS

Planned CS refers to a CS that is scheduled before the onset of labour for a specific clinical indication. This section deals only with decisions about the mode of delivery. Other aspects of management of specific conditions or complications of pregnancy are outside the scope of this guideline.

Breech Presentation

A - Women who have an uncomplicated singleton breech pregnancy at 36 weeks gestation should be offered external cephalic version. Exceptions include women in labour and women with a uterine scar or abnormality, fetal compromise, ruptured membranes, vaginal bleeding, or medical conditions.

A - Pregnant women with a singleton breech presentation at term for whom external cephalic version is contraindicated or has been unsuccessful should be offered CS because it reduces perinatal mortality and neonatal morbidity.

Multiple Pregnancy

- C In otherwise uncomplicated twin pregnancies at term where the presentation of the first twin is cephalic, perinatal morbidity and mortality is increased for the second twin. However, the effect of planned CS in improving outcome for the second twin remains uncertain and therefore CS should not routinely be offered outside a research context.
- GPP In twin pregnancies where the first twin is not cephalic, the effect of CS in improving outcome is uncertain, but current practice is to offer a planned CS.
- B Planned CS for uncomplicated twin pregnancy should not be carried out before 38 weeks because this increases the risk of respiratory problems in these babies.

Preterm Birth and CS

C - Preterm birth is associated with higher neonatal morbidity and mortality. However, the effect of planned CS in improving these outcomes remains uncertain and therefore CS should not routinely be offered outside a research context.

Small for Gestational Age and CS

C - The risk of neonatal morbidity and mortality is higher with "small for gestational age" babies. However, the effect of planned CS in improving these outcomes remains uncertain, and therefore CS should not routinely be offered outside a research context.

Placenta Praevia

D - Women with a placenta that partly or completely covers the internal cervical os (grade 3 or 4 placenta praevia) should be offered CS.

Predicting CS for Cephalopelvic Disproportion in Labour

- A Pelvimetry is not useful in predicting "failure to progress" in labour and should not be used in decision making about mode of birth.
- B Shoe size, maternal height, and estimations of fetal size (ultrasound or clinical examination) do not accurately predict cephalopelvic disproportion and should not be used to predict "failure to progress" during labour.

Mother-to-Child Transmission of Maternal Infections

This section exclusively addresses CS as an intervention to reduce mother-to-child transmission of infections. Other interventions to reduce transmission of these infections to the baby are available but are outside the scope of this guideline.

- A Human immunodeficiency virus (HIV)-positive women who are pregnant should be offered a planned CS because it reduces the risk of mother-to-child transmission of HIV.
- B Mother-to-child transmission of hepatitis B can be reduced if the baby receives immunoglobulin and vaccination. In these situations pregnant women with hepatitis B should not be offered a planned CS, because there is insufficient evidence that this reduces mother-to-child transmission of hepatitis B virus.
- C Women who are infected with hepatitis C should not be offered a planned CS because this does not reduce mother-to-child transmission of the virus.
- C Pregnant women who are coinfected with hepatitis C virus and HIV should be offered planned CS because it reduces mother-to-child transmission of both hepatitis C virus and HIV.
- C Women with primary genital herpes simplex virus (HSV) infection occurring in the third trimester of pregnancy should be offered planned CS because it decreases the risk of neonatal HSV infection.
- C Pregnant women with a recurrence of HSV at birth should be informed that there is uncertainty about the effect of planned CS in reducing the risk of neonatal HSV infection. Therefore, CS should not routinely be offered outside a research context.

Maternal Request for CS

- GPP Maternal request is not on its own an indication for CS, and specific reasons for the request should be explored, discussed, and recorded.
- GPP When a woman requests a CS in the absence of an identifiable reason, the overall benefits and risks of CS compared with vaginal birth should be discussed and recorded.
- A When a woman requests a CS because she has a fear of childbirth, she should be offered counselling (such as cognitive behavioural therapy) to help her to address her fears in a supportive manner, because this results in reduced fear of pain in labour and shorter labour.
- GPP An individual clinician has the right to decline a request for CS in the absence of an identifiable reason. However the woman's decision should be respected, and she should be offered referral for a second opinion.

Factors Affecting Likelihood of CS During Intrapartum Care

Place of Birth

B - During their discussions about options for birth, healthy pregnant women with anticipated uncomplicated pregnancies should be informed that delivering at home reduces the likelihood of CS.

A - During their discussions about options for birth, healthy pregnant women with anticipated uncomplicated pregnancies should be informed that planned childbirth in a "midwifery-led unit" does not reduce the likelihood of CS.

Reducing Likelihood of CS

The following interventions during intrapartum care have been shown to decrease the likelihood of CS:

- A Women should be informed that continuous support during labour from women with or without prior training reduces the likelihood of CS.
- A Women with an uncomplicated pregnancy should be offered induction of labour beyond 41 weeks because this reduces the risk of perinatal mortality and the likelihood of CS (see also the NICE Clinical Guideline on induction of labour; details in Section 6 of that document).
- A A partogram with a 4-hour action line should be used to monitor progress of labour of women in spontaneous labour with an uncomplicated singleton pregnancy at term, because it reduces the likelihood of CS.
- C Consultant obstetricians should be involved in the decision making for CS, because this reduces the likelihood of CS.
- B Electronic fetal monitoring is associated with an increased likelihood of CS. When CS is contemplated because of an abnormal fetal heart rate pattern, in cases of suspected fetal acidosis, fetal blood sampling should be offered if it is technically possible and there are no contraindications (see also the NICE Clinical Guideline on electronic fetal monitoring; details in Section 6 of that document).

No Influence on Likelihood of CS

- A Women should be informed that the following interventions during intrapartum care have not been shown to influence the likelihood of CS, although they may affect other outcomes that are outside the scope of this guideline:
- Walking in labour
- Nonsupine position during the second stage of labour
- Immersion in water during labour
- Epidural analgesia during labour
- Use of raspberry leaf
- D Women should be informed that the effects on the likelihood of CS of complementary therapies used during labour (such as acupuncture, aromatherapy, hypnosis, herbal products, nutritional supplements, homeopathic medicines, and Chinese medicines) have not been properly evaluated and further research is needed before such interventions can be recommended.

[&]quot;Failure to Progress" in Labour and CS

- A The following aspects of intrapartum care have not been shown to influence the likelihood of CS for "failure to progress" and should not be offered for this reason, although they may affect other outcomes which are outside the scope of this guideline:
- Active management of labour
- Early amniotomy

Eating during Labour

- A Women should be informed that eating a low-residue diet during labour (toast, crackers, low-fat cheese) results in larger gastric volumes, but the effect on the risk of aspiration if anaesthesia is required is uncertain.
- A Women should be informed that having isotonic drinks during labour prevents ketosis without a concomitant increase in gastric volume.

Procedural Aspects of CS

Timing of CS

B - The risk of respiratory morbidity is increased in babies born by CS before labour, but this risk decreases significantly after 39 weeks. Therefore planned CS should not routinely be carried out before 39 weeks.

Decision-to-Delivery Interval for Emergency CS

C - Delivery at emergency CS for maternal or fetal compromise should be accomplished as quickly as possible, taking into account that rapid delivery has the potential to do harm. A decision-to-delivery interval of less than 30 minutes is not in itself critical in influencing baby outcome, but has been an accepted audit standard for response to emergencies within maternity services.

Preoperative Testing Before CS

- C Pregnant women should be offered a haemoglobin assessment before CS to identify those who have anaemia. Although blood loss of more than 1,000 ml is infrequent after CS (it occurs in 4-8% of CS), it is a potentially serious complication.
- C Pregnant women having CS for antepartum haemorrhage, abruption, uterine rupture, and placenta praevia are at increased risk of blood loss of more than 1,000 ml and should have the CS carried out at a maternity unit with on-site blood transfusion services.
- C Pregnant women who are healthy and who have otherwise uncomplicated pregnancies should not routinely be offered the following tests before CS:
- Grouping and saving of serum
- Cross-matching of blood
- A clotting screen

 Preoperative ultrasound for localisation of the placenta, because this does not improve CS morbidity outcomes (such as blood loss of more than 1,000 ml, injury of the infant, and injury to the cord or to other adjacent structures).

GPP - Women having CS with regional anaesthesia require an indwelling urinary catheter to prevent over-distension of the bladder, because the anaesthetic block interferes with normal bladder function.

Anaesthesia for CS

- GPP Pregnant women having a CS should be given information on different types of post-CS analgesia so that analgesia best suited to their needs can be offered (see recommendation below under "Care of the Woman after CS").
- A Women who are having a CS should be offered regional anaesthesia because it is safer and results in less maternal and neonatal morbidity than general anaesthesia. This includes women who have a diagnosis of placenta praevia.
- B Women who are having induction of regional anaesthesia for CS should be cared for in theatre because this does not increase patient anxiety.
- A Women who are having a CS under regional anaesthesia should be offered intravenous ephedrine or phenylephrine, and volume preloading with crystalloid or colloid to reduce the risk of hypotension occurring during CS.
- D Each maternity unit should have a drill for failed intubation during obstetric anaesthesia.
- B To reduce the risk of aspiration pneumonitis, women should be offered antacids and drugs (such as H_2 receptor antagonists or proton pump inhibitors) to reduce gastric volumes and acidity before CS.
- A Women having a CS should be offered antiemetics (either pharmacological or acupressure) to reduce nausea and vomiting during CS.
- GPP General anaesthesia for emergency CS should include preoxygenation, cricoid pressure, and rapid sequence induction to reduce the risk of aspiration.
- A Intravenous ephedrine or phenylephrine should be used in the management of hypotension during CS.
- A The operating table for CS should have a lateral tilt of 15° , because this reduces maternal hypotension.

Surgical Techniques for CS

The following recommendations for surgical techniques apply to pregnancies at term where there is a lower uterine segment. Techniques may need modification in situations such as repeat CS or placenta praevia.

- A Health-care professionals should wear double gloves when performing or assisting at CS on women who have tested positive for HIV, to reduce the risk of HIV infection of health-care professionals during surgery.
- C General recommendations for safe surgical practice should be followed at CS to reduce the risk of HIV infection of staff.
- B CS should be performed using a transverse abdominal incision because this is associated with less postoperative pain and an improved cosmetic effect compared with a midline incision.
- A The transverse incision of choice should be the Joel Cohen incision (a straight skin incision, 3 cm above the symphysis pubis; subsequent tissue layers are opened bluntly and, if necessary, extended with scissors and not a knife), because it is associated with shorter operating times and reduced postoperative febrile morbidity.
- B The use of separate surgical knives to incise the skin and the deeper tissues at CS is not recommended because it does not decrease wound infection.
- A When there is a well formed lower uterine segment, blunt rather than sharp extension of the uterine incision should be used because it reduces blood loss, incidence of postpartum haemorrhage, and the need for transfusion at CS.
- C Women who are having a CS birth should be informed that the risk of fetal lacerations is about 2%.
- C Forceps should only be used at CS if there is difficulty delivering the baby's head. The effect on neonatal morbidity of the routine use of forceps at CS remains uncertain.
- C Oxytocin 5 IU by slow intravenous injection should be used at CS to encourage contraction of the uterus and to decrease blood loss.
- A At CS, the placenta should be removed using controlled cord traction and not manual removal as this reduces the risk of endometritis.
- A Intraperitoneal repair of the uterus at CS should be undertaken. Exteriorisation of the uterus is not recommended because it is associated with more pain and does not improve operative outcomes such as haemorrhage and infection.
- B The effectiveness and safety of single layer closure of the uterine incision is uncertain. Except within a research context, the uterine incision should be sutured with two layers.
- A Neither the visceral nor the parietal peritoneum should be sutured at CS because this reduces operating time and the need for postoperative analgesia and improves maternal satisfaction.

- B In the rare circumstances that a midline abdominal incision is used at CS, mass closure with slowly absorbable continuous sutures should be used because this results in fewer incisional hernias and less dehiscence than layered closure.
- A Routine closure of the subcutaneous tissue space should not be used, unless the woman has more than 2 cm subcutaneous fat, because it does not reduce the incidence of wound infection.
- A Superficial wound drains should not be used at CS because they do not decrease the incidence of wound infection or wound haematoma.
- C Obstetricians should be aware that the effects of different suture materials or methods of skin closure at CS are not certain.
- B Umbilical artery pH should be performed after all CS for suspected fetal compromise, to allow review of fetal well-being and guide ongoing care of the baby.
- A Women having a CS should be offered prophylactic antibiotics, such as a single dose of first-generation cephalosporin or ampicillin, to reduce the risk of postoperative infections (such as endometritis, urinary tract and wound infection), which occur in about 8% of women who have had a CS.
- D Women having a CS should be offered thromboprophylaxis because they are at increased risk of venous thromboembolism. The choice of method of prophylaxis (for example, graduated stockings, hydration, early mobilisation, low molecular weight heparin) should take into account risk of thromboembolic disease and follow existing guidelines.
- GPP Women's preferences for the birth, such as music playing in theatre, lowering the screen to see the baby born, or silence so that the mothers voice is the first the baby hears, should be accommodated where possible.

Care of the Baby Born by CS

- C An appropriately trained practitioner skilled in the resuscitation of the newborn should be present at CS performed under general anaesthesia or where there is evidence of fetal compromise.
- GPP Babies born by CS are more likely to have a lower temperature, and thermal care should be in accordance with good practice for thermal care of the newborn baby.
- A Early skin-to-skin contact between the woman and her baby should be encouraged and facilitated because it improves maternal perceptions of the infant, mothering skills, maternal behaviour, and breastfeeding outcomes, and reduces infant crying.
- A Women who have had a CS should be offered additional support to help them to start breastfeeding as soon as possible after the birth of their baby. This is because women who have had a CS are less likely to start breastfeeding in the

first few hours after the birth, but, when breastfeeding is established, they are as likely to continue as women who have a vaginal birth.

Care of the Woman after CS

- D After CS, women should be observed on a one-to-one basis by a properly trained member of staff until they have regained airway control and cardiorespiratory stability and are able to communicate.
- B Health-care professionals caring for women after CS should be aware that, although it is rare for women to need intensive care following childbirth, this occurs more frequently after CS (about 9 per 1,000).
- GPP After recovery from anaesthesia, observations (respiratory rate, heart rate, blood pressure, pain, and sedation) should be continued every half hour for 2 hours, and hourly thereafter provided that the observations are stable or satisfactory. If these observations are not stable, more frequent observations and medical review are recommended.
- GPP For women who have had intrathecal opioids, there should be a minimum hourly observation of respiratory rate, sedation, and pain scores for at least 12 hours for diamorphine and 24 hours for morphine.
- GPP For women who have epidural opioids or patient-controlled analgesia with opioids, there should be routine hourly monitoring of respiratory rate, sedation, and pain scores throughout treatment and for at least 2 hours after discontinuation of treatment.
- A Women should be offered diamorphine (0.3-0.4 mg intrathecally) for intraand postoperative analgesia because it reduces the need for supplemental analgesia after a CS. Epidural diamorphine (2.5-5 mg) is a suitable alternative.
- GPP Patient-controlled analgesia using opioid analgesics should be offered after CS because it improves pain relief.
- A Providing there is no contraindication, nonsteroidal anti-inflammatory drugs should be offered post-CS as an adjunct to other analgesics, because they reduce the need for opioids.
- A Women who are recovering well after CS and do not have complications can eat and drink when they feel hungry or thirsty.
- D Removal of the urinary bladder catheter should be carried out once a woman is mobile after a regional anaesthetic and not sooner than 12 hours after the last "top up" dose.
- A Routine respiratory physiotherapy does not need to be offered to women after a CS under general anaesthesia, because it does not improve respiratory outcomes such as coughing, phlegm, body temperature, chest palpation, and auscultatory changes.

GPP - Women who have had a CS should be offered the opportunity to discuss with their health-care providers the reasons for the CS and implications for the child or future pregnancies.

A - Length of hospital stay is likely to be longer after a CS (an average of 3-4 days) than after a vaginal birth (average 1-2 days). However, women who are recovering well, are apyrexial, and do not have complications following CS should be offered early discharge (after 24 hours) from hospital and follow-up at home, because this is not associated with more infant or maternal readmissions.

Recovery Following CS

GPP - In addition to general postnatal care, women who have had a CS should be provided with:

- Specific care related to recovery after CS
- Care related to management of other complications during pregnancy or childbirth

D - Women who have a CS should be prescribed and encouraged to take regular analgesia for postoperative pain, using:

- For severe pain, co-codamol with added ibuprofen
- For moderate pain, co-codamol
- For mild pain, paracetamol

D - CS wound care should include:

- Removing the dressing 24 hours after the CS
- Specific monitoring for fever
- Assessing the wound for signs of infection (such as increasing pain, redness, or discharge), separation, or dehiscence
- Encouraging the woman to wear loose, comfortable clothes and cotton underwear
- Gently cleaning and drying the wound daily
- If needed, planning the removal of sutures or clips

D - Health-care professionals caring for women who have had a CS and who have urinary symptoms should consider the possible diagnosis of:

- Urinary tract infection
- Stress incontinence (occurs in about 4% of women after CS)
- Urinary tract injury (occurs in about 1 per 1,000 CS)

D - Health-care professionals caring for women who have had a CS and who have irregular vaginal bleeding should consider that this is more likely to be due to endometritis than retained products of conception.

D - Women who have had a CS are at increased risk of thromboembolic disease (both deep vein thrombosis and pulmonary embolism), so health-care professionals need to pay particular attention to women who have chest

symptoms (such as cough or shortness of breath) or leg symptoms (such as painful swollen calf).

- GPP Women who have had a CS should resume activities such as driving a vehicle, carrying heavy items, formal exercise, and sexual intercourse once they have fully recovered from the CS (including any physical restrictions or distracting effect due to pain).
- D Health-care professionals caring for women who have had a CS should inform women that after a CS they are not at increased risk of difficulties with breastfeeding, depression, post-traumatic stress symptoms, dyspareunia, and faecal incontinence.

Pregnancy and Childbirth Following CS

GPP - The risks and benefits of vaginal birth after CS compared with repeat CS are uncertain. Therefore the decision about mode of birth after a previous CS should take into consideration:

- Maternal preferences and priorities
- A general discussion of the overall risks and benefits of CS (see Appendix A of the original guideline document)
- Risk of uterine rupture
- Risk of perinatal mortality and morbidity
- B Pregnant women who have a previous CS and who want to have a vaginal birth should be supported in this decision. They should be informed that:
- Uterine rupture is a very rare complication, but is increased in women having a planned vaginal birth (35 per 10,000 women compared with 12 per 10,000 women having planned repeat CS).
- The risk of an intrapartum infant death is small for women who have a planned vaginal birth (about 10 per 10,000), but higher than for a planned repeat CS (about 1 per 10,000).
- The effect of planned vaginal birth or planned repeat CS on cerebral palsy is uncertain.

GPP - Women who have had a previous CS should be offered:

- Electronic fetal monitoring during labour
- Care during labour in a unit where there is immediate access to CS and onsite blood transfusion services
- B Women who have had a previous CS can be offered induction of labour, but both women and health-care professionals should be aware that the likelihood of uterine rupture in these circumstances is increased to:
- 80 per 10,000 when labour is induced with nonprostaglandin agents
- 240 per 10,000 when labour is induced using prostaglandins.

GPP - During induction of labour, women who have had a previous CS should be monitored closely, with access to electronic fetal monitoring and with immediate access to CS, because they are at increased risk of uterine rupture.

B - Pregnant women with both previous CS and a previous vaginal birth should be informed that they have an increased likelihood of a vaginal birth than women who have had a previous CS but no previous vaginal birth.

Definitions:

Levels of Evidence

1a: Evidence obtained from systematic review or meta-analysis of randomised controlled trials

1b: Evidence obtained from at least one randomised controlled trial

2a: Evidence obtained from at least one well-designed controlled study without randomisation

2b: Evidence obtained from at least one well-designed quasi-experimental study, such as a cohort study

- 3: Evidence obtained from well-designed nonexperimental descriptive studies, such as comparative studies, correlation studies, case-control studies, and case series
- 4: Evidence obtained from expert committee reports, or opinions and/or clinical experience of respected authorities

Grading of Recommendations

Grade A Based directly on level 1 evidence

Grade B Based directly on level 2 evidence or extrapolated from level 1 evidence

Grade C Based directly on level 3 evidence or extrapolated from level 1 or level 2 evidence

Grade D Based directly on level 4 evidence or extrapolated from level 1, level 2, or level 3 evidence

Good Practice Points (GPP) The view of the Guideline Development Group

CLINICAL ALGORITHM(S)

A practice algorithm is provided in the original guideline document for caesarean section.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations")

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits

Consistent quality of care for women considering caesarean section

Subgroups Most Likely to Benefit

- Pregnant women with a singleton breech presentation at term, for whom
 external cephalic version is contraindicated or has been unsuccessful, should
 be offered caesarean section (CS) because it reduces perinatal mortality and
 neonatal morbidity.
- Human immunodeficiency virus (HIV)-positive women who are pregnant should be offered a planned CS because it reduces the risk of mother-to-child transmission of HIV.
- Pregnant women who are coinfected with hepatitis C virus and HIV should be offered planned CS because it reduces mother-to-child transmission of both hepatitis C virus and HIV.
- Women with primary genital herpes simplex virus infection occurring in the third trimester of pregnancy should be offered planned CS because it decreases the risk of neonatal herpes simplex virus infection.

POTENTIAL HARMS

- Complications of caesarean section (CS) include anesthesia risks, blood loss during surgery, postoperative wound infections and endometritis, urinary and genital tract injury, fetal laceration, postoperative urinary tract infections, pain, and venous thromboembolism.
- Women who have had a CS and have a subsequent vaginal birth are at higher risk for uterine rupture (35 per 10,000 women) and intrapartum infant death (10 per 10,000) than women who have a repeat CS.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to fetal blood sampling include maternal infection (such as human immunodeficiency virus [HIV], hepatitis viruses, or herpes simplex virus); fetal bleeding disorders such as haemophilia, and prematurity (less than 34 weeks). Where there is clear evidence of acute fetal compromise (e.g., prolonged

decelerations [longer than 3 minutes]), fetal blood sampling should not be undertaken and the baby should be delivered urgently.

QUALIFYING STATEMENTS

OUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer
- This guideline focuses on cesarean section (CS), and factors that affect decisions about CS. It does not consider the effect these factors might have on other aspects of antenatal and intrapartum care.
- CS is the end of a number of clinical pathways; therefore it is not possible to cover all the clinical decisions that may lead to a CS in one guideline. The guideline does not offer advice on the risks and benefits of CS for specific clinical conditions arising during pregnancy such as pre-eclampsia. Nor does it address the needs of pregnant women or babies with rare conditions such as maternal congenital heart disease or monozygotic twins.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Local health communities should review their existing practice on Caesarean section (CS) against this guideline as they develop their Local Delivery Plans. The review should consider the resources required to implement the recommendations set out in the original guideline document (and in the "Major Recommendations" section of this summary), the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of women that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines, care pathways, and protocols should be reviewed in the light of this guidance and revised accordingly.

The guideline will complement the Children's National Service Framework (England and Wales), which is in development and which will produce standards for service configuration, with emphasis on how care is delivered and by whom, including issues of ensuring equity of access to care for disadvantaged women and women's views about service provision. (For more information, see https://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/ChildrenServices/ChildrenServicesInformation/fs/en for England and www.wales.nhs.uk/sites/page.cfm?orgid=334&pid=934 for Wales.)

Further information on Caesarean section may be obtained from evidence-based websites such as the Cochrane Library (www.update-

<u>software.com/clibng/cliblogon.htm</u>) and the National Electronic Library for Health (www.nelh.nhs.uk/maternity).

The Pregnancy Book (published by health departments in England and Wales) may also be a useful resource for parents.

Suggested audit criteria are listed in Section 11 of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice.

Key Priorities for Implementation

Making the Decision

- When considering a Caesarean section (CS), there should be discussion on the benefits and risks of CS compared with vaginal birth specific to the woman and her pregnancy.
- Maternal request is not on its own an indication for CS, and specific reasons for the request should be explored, discussed, and recorded. When a woman requests a CS in the absence of an identifiable reason, the overall benefits and risks of CS compared with vaginal birth should be discussed and recorded.

Carrying Out the Procedure

- The following interventions should be used to decrease morbidity from CS:
 - regional anaesthesia
 - antibiotic prophylaxis
 - thromboprophylaxis
 - antacids
 - antiemetics
- The risk of respiratory morbidity is increased in babies born by CS before labour but this risk decreases significantly after 39 weeks. Therefore, planned CS should not routinely be carried out before 39 weeks.

Reducing the Likelihood of CS

- Women who have an uncomplicated singleton breech pregnancy at 36 weeks'
 gestation should be offered external cephalic version. Exceptions include
 women in labour, and women with a uterine scar or abnormality, fetal
 compromise, ruptured membranes, vaginal bleeding, or medical conditions.
- Women should be informed that continuous support during labour from women with or without prior training reduces the likelihood of CS.
- Women with uncomplicated pregnancies should be offered induction of labour beyond 41 weeks, because this reduces the risk of perinatal mortality and the likelihood of CS.
- A partogram with a 4-hour action line should be used to monitor progress of labour of women in spontaneous labour with an uncomplicated singleton pregnancy at term, because it reduces the likelihood of CS.
- Consultant obstetricians should be involved in the decision making for CS, because this reduces the likelihood of CS.

• Electronic fetal monitoring is associated with an increased likelihood of CS. When CS is contemplated because of an abnormal fetal heart rate pattern, in cases of suspected fetal acidosis, fetal blood sampling should be offered if it is technically possible and there are no contraindications.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Clinical Algorithm Foreign Language Translations Patient Resources Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

LOM DOMALN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Women's and Children's Health. Caesarean section. London (UK): National Institute for Clinical Excellence (NICE); 2004 Apr. 142 p. [688 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

National Collaborating Centre for Women's and Children's Health - National Government Agency [Non-U.S.]

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GUI DELI NE COMMITTEE

Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr John Sandars (Group Leader), General Practitioner, Stockport, Cheshire, and Part-Time Lecturer, University of Manchester; Mrs. Debbie Chippington Derrick, Caesarean Birth and VBAC Coordinator, National Childbirth Trust, London; Mrs Jill Demilew, Consultant Midwife, Kings College Hospital, London; Mrs Christine Ruby, Senior Lecturer in Midwifery and Women's Health, University College Worcester, and Midwife, Powys Local Health Board; Dr. Michael Wee, Lead Consultant Obstetric Anaesthetist, Poole Hospital NHS Trust, Poole, Dorset; Dr Bryan Beattie, Consultant Obstetrician and Fetal Medicine, University Hospital of Wales, Cardiff; Mrs Shaheen Chaudhry, Freelance Consultant, Facilitator and Trainer, Bristol; Dr John Madar, Consultant Neonatologist, Derriford Hospital, Plymouth, Devon; Dr Gwyneth Lewis, Director of the United Kingdom Confidential Enquiries into Maternal Deaths; Professor David James, Professor of Fetomaternal Medicine and Director of Medical Education, Queens Medical Centre, Nottingham; Ms Jane Thomas, Director, National Collaborating Centre for Women's and Children's Health (NCC-WCH), and Honorary Consultant Obstetrician and Gynaecologist, Oxford; Dr Heather Brown, Research Fellow, NCC-WCH; Dr Shantini Paranjothy, Research Fellow, NCC-WCH; Mr Alex McNeil, Informatics Specialist, NCC-WCH; Miss Anna Bancsi, Work Programme Co-ordinator, NCC-WCH, Dr Hannah-Rose Douglas, Health Economist, London School of Hygiene Tropical Medicine

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In accordance with guidance from the National Institute for Clinical Excellence (NICE), all Guideline Development Group members' interests were recorded on a standard declaration form that covered consultancies, fee-paid work, shareholdings, fellowships, and support from the health-care industry.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Women's and Children's Health. Caesarean section. NICE guideline. London (UK): National Institute for Clinical Excellence (NICE); 2004 Apr. 38 p. (Clinical guideline, no. 13). Available in Portable Document Format (PDF) from the <u>National Institute for Clinical Excellence</u> (NICE) Web site.
- Caesarean section. Quick reference guide. National Collaborating Centre for Women's and Children's Health, 2004 Apr. 8 p. Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.
- Caesarean section. Evidence tables. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Clinical Excellence, 2004 Apr. 153 p. Available in Portable Document Format (PDF) from the NICE Web site.
- Caesarean section. Summary of effects and procedural aspects. National Collaborating Centre for Women's and Children's Health, 2004 Apr. 4. p. Available in Portable Document Format (PDF) from the <u>NICE Web site</u>.

Print copies: Available from the National Health Service (NHS), 11 Strand, London, WC2N 5HR. Response Line 0870 1555 455.

Additionally, Audit Criteria can be found in Section 11 of the <u>original guideline</u> document.

PATIENT RESOURCES

The following is available:

• Caesarean section: Understanding NICE guidance - information for pregnant women, their partners and the public. National Institute for Clinical Excellence (NICE), 2004 Apr. 52 p.

Electronic copies: Available in English and Welsh from the <u>National Institute for Clinical Excellence (NICE) Web site</u>.

Print copies: Available from the National Health Service (NHS), 11 Strand, London, WC2N 5HR. Response Line 0870 1555 455, ref N0479.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on July 9, 2004. The information was verified by the guideline developer on December 3, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was

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